Remarks

Pursuant to 37 C.F.R. § 41.39(b)(1), applicants request that the present application be reopened for prosecution and that the appeal be withdrawn. Therefore, in view of the following remarks, reconsideration of the outstanding rejections contained in the Examiner's Answer (mailed November 20, 2006) is respectfully requested.

Claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84 are now currently pending. No amendments to the claims have been made in the present reply. However, applicants have included the above listing of claims in order to confirm the status and content of each claim. The pending claims (as listed herein) correspond to the claims that were pending on appeal. Applicants note that the rejections set forth in the Examiner's Answer included rejections to claims that were no longer pending on appeal, i.e., they had been canceled prior to appeal. Therefore, applicants are listing the claims to make sure that the record is clear as to what claims are currently pending, even though there are no current claim amendments or cancellations made in the present Request to Reopen Prosecution and Reply Under 37 C.F.R. § 1.111.

The rejection of claims 41-47, 49-54, 58-73, 75-77, and 80-85 under 35 U.S.C. § 112 (1st para.) for failure to satisfy the written description requirement is respectfully traversed. This rejection is moot with respect to previously canceled claims 42-47, 52, 54, 62-68, 72, 81, 83, and 85. With regard to claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84, this rejection is respectfully traversed in view of the following remarks.

The burden of establishing that an application lacks adequate written descriptive support falls on the U.S. Patent and Trademark Office ("USPTO"). *See In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (stating that the USPTO "has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). Hence, the USPTO must demonstrate *why* the disclosure is insufficient. Applicants assert that the USPTO has failed to meet this burden.

In the Amendment dated August 13, 2004, applicants amended independent claims 41, 61, and 75 to recite "a promoter that is not pathogen-inducible." The USPTO has asserted that the only reference to plant promoters in the specification is at page 36, line 19, which states "various promoters including pathogen-induced promoters" (Examiner's Answer, at page 4). In terms of the written description requirement analysis, it is important

to place this statement in proper context. In the specification, the above statement referred to by the Examiner appeared in the following passage (at page 36, lines 17-21):

> ***As is conventional in the art***, such transgenic plants would contain suitable vectors with ***various promoters*** including pathogen-induced promoters, and other components needed for transformation, transcription, and, possibly, translation.

(emphasis added).

It is important to note that the above passage does not state that ***only*** pathogen-induced promoters can be used in the present invention. Instead, the passage states that "various promoters" can be used. The skilled artisan would immediately envisage that such "various promoters" would include all types of promoters that could be used in transforming plants, not just pathogen-induced promoters. Other promoters that would readily come to mind would be constitutive promoters and other types of non-pathogen-inducible promoters (e.g., chemically induced promoters). Examples of such other promoters include (i) the cauliflower mosaic virus (CaMV) 35S promoter (*see* U.S. Patent No. 5,352,605 to Fraley et al. ("Fraley") (previously attached to applicants' Appeal Brief as **Exhibit 3**)); (ii) the nopaline synthase (NOS) promoter from *Agrobacterium tumefaciens* (*see* Koncz et al., "The Opine Synthase Genes Carried by Ti Plasmids Contain All Signals Necessary for Expression in Plants," *EMBO J.* 2(9):1597-1603 (1983) ("Koncz") (previously attached to applicants' Appeal Brief as **Exhibit 1**); *see also* U.S. Patent No. 5,034,322 to Rogers et al. ("Rogers") (previously attached to applicants' Appeal Brief as **Exhibit 2**)); (iii) the maize alcohol dehydrogenase 1 (Adh-1) promoter (*see* U.S. Patent No. 5,001,060 to Peacock et al.); (iv) the plant ubiquitin (Ubi) promoter (*see* U.S. Patent No. 5,510,474 to Quail et al.); and (v) the tetracycline-regulated promoter (*see* U.S. Patent No. 5,464,758 to Gossen et al.)

During prosecution and again on appeal, applicants set forth the argument (as noted in the previous paragraph) that it was well known at the time of filing that constitutive promoters and other non-pathogen-induced promoters were widely used for plant transformation. Applicants cited to Koncz, Rogers, and Fraley as support for this position. Thus, the phrase "various promoters" in the specification would have been understood by those skilled in the art to encompass, besides pathogen-induced promoters, promoters that are *not* pathogen-inducible (e.g., constitutive promoters). Koncz, Rogers, and Fraley constitute strong evidence that the present application intended to cover the use of pathogen-inducible ***and*** non-pathogen-inducible promoters in transgenic plants. A detailed explanation of the teachings of Koncz, Rogers, and Fraley is included in the Appeal Brief at pages 5-6.

Nevertheless, in response to applicants' arguments on appeal, the USPTO has asserted that "the art at the time of filing ***only*** contemplated that pathogen-inducible promoters would function in the claimed invention" (Examiner's Answer, at page 7) (emphasis added). In particular, the USPTO has taken the position that, "at the time of filing, one of ordinary skill in the art would have expected that use of constitutive promoters in expression of a harpin in a plant would kill the plant" (Examiner's Answer, at page 8). Therefore, the USPTO asserts that "the instant specification would need to specifically mention constitutive promoters and/or other types of non-pathogen-inducible promoters for the instantly claimed invention to have been contemplated at the time of filing" (Examiner's Answer, at page 8). The USPTO has failed to cite a single rule, guideline, or precedential case to support this requirement. In contrast, as described below, the case law regarding the written description requirement weighs in favor of applicants' position, i.e., that the disclosure is adequate to support the claim recitation of a "promoter that is not pathogen-inducible."

For example, the law states that, "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Manual of Patent Examining Procedure ("MPEP") § 2163, at 2100-165 (8th Edition, Rev. 5, Aug. 2006); *see, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The law further states that, "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." MPEP § 2163, at 2100-173; s*ee Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). "If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." MPEP § 2163, at 2100-173; *see, e.g., Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating that "the description need not be in *ipsis verbis* to be sufficient"). "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, at 2100-169; *see, e.g., Vas-Cath*, 935 F.2d at 1563-1564, 19 USPQ2d at 1117.

Here, there is no question that, at the time of filing, it was conventional to use constitutive promoters and other non-pathogen-inducible promoters to transform plants. This is evidenced by Koncz, Fraley, and Rogers. In requiring that the specification explicitly recite the use of constitutive promoters, the USPTO seems to ignore the state of the art, as well as the plain language of the specification that says that "various promoters" could be used. The specification does not limit these "various promoters" to pathogen-induced promoters, but only includes such promoters as one type of promoter. Thus, there simply is no support for the view that, at the time of filing, the inventors were not in possession of the invention as currently claimed.

For these reasons, applicants respectfully submit that the rejection of claims 41-47, 49-54, 58-73, 75-77, and 80-85 for lack of adequate written descriptive support is improper and should be withdrawn.

The rejection of claims 41-47, 49-54, 58-73, 75-77, and 80-85 under 35 U.S.C. § 112 (1st para.) for lack of enablement is respectfully traversed. This rejection is moot with respect to previously canceled claims 42-47, 52, 54, 62-68, 72, 81, 83, and 85. With regard to claims 41, 49-51, 53, 58-61, 69-71, 73, 75-77, 80, 82, and 84, this rejection is respectfully traversed in view of the following remarks.

The enablement requirement of 35 U.S.C. § 112 (1st para.) requires that the disclosure, when filed, contain sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. *See* MPEP § 2164, at 2100-186. This requirement has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The disclosure need not teach, and preferably omits, what is well known in the art. *See In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

The USPTO has taken the position that the application does not enable using a non-pathogen-inducible promoter for transgenic expression of HR elicitors in plants. The USPTO's rationale is that, at the time of filing, constitutive expression of HR elicitors in plants was considered lethal. To support this view, the USPTO cites the following references: (i) U.S. Patent No. 5,850,015 to Bauer et al. ("Bauer"); (ii) U.S. Patent No. 6,174,717 to Beer et al. ("Beer"); and (iii) Tampakaki et al., "Elicitation of Hypersensitive Cell Death by Extracellularly Targeted $HrpZ_{Psph}$ Produced In Planta," *Molecular Plant-Microbe Interactions* 13:1366-1374 (2000) ("Tampakaki"). In view of these references, the USPTO has alleged that, until the year 2000 (the publication date of Tampakaki), the

prevalent view in the art was that constitutive expression of HR elicitors was lethal to the plants. Applicants respectfully disagree.

With respect to Bauer and Beer, applicants assert that these references do not accurately represent the state of the art at the time of filing of the present application. Bauer was originally filed on ***June 7, 1995***, as U.S. Patent Application Serial No. 08/484,358. Beer is a patent whose original disclosure was filed on ***July 1, 1992***, as U.S. Patent Application Serial No. 07/907,935, now abandoned. Therefore, Bauer and Beer were filed substantially before the December 3, 1997, filing date of the present application. Thus, based on their filing dates alone, Bauer and Beer cannot be viewed as accurately representing the state of the art at the time of filing the present application.

Compared to knowledge at the time of filing of Bauer and Beer, at the time of the filing of the present application, much more information was available regarding the constitutive expression of HR elicitors in plants. As mentioned previously herein, the use of constitutive promoters and other non-pathogen-inducible promoters in transforming plants was well known in December 1997. In addition to the teaching contained in the present application, this view is supported by the experimental data of record in this case, specifically in the Declaration of Zhong-Min Wei Under 37 C.F.R. § 1.132 (dated August 11, 2004) (referred to herein and previously as the "Second Wei Declaration") (submitted with the Amendment dated August 13, 2004). The Second Wei Declaration presents data of the transformation of *Arabidopsis* and tobacco plants with a gene construct containing the *hrpN* gene operatively coupled to the NOS promoter (*see* Second Wei Declaration ¶¶ 25-30). The Second Wei Declaration states that "[t]he NOS promoter is considered a ***weak constitutive promoter***" (Second Wei Declaration ¶ 26) (emphasis added). The data shows that the constitutive expression of HrpN using the NOS promoter was not lethal to the transgenic plants, and that the transgenic plants exhibited pathogen resistance (*see* Second Wei Declaration ¶¶ 28-30).

The USPTO quotes Tampakaki as stating that it was "expect[ed] that endogenously produced harpin ***may*** be lethal to the plant (page 1367, left column, paragraph 4) (emphasis added). This is far from a definitive statement of the state of the art. Nowhere does Tampakaki state that it was the prevalent view or well known in the art that constitutive expression of harpin in plants would necessarily result in plant death. Further, nowhere does Tampakaki teach or suggest that it was the view that ***only*** pathogen-induced promoters could be used for transforming plants with harpin genes. Instead, at the time of filing of the present application, applicants assert that it would have been reasonable for one of ordinary skill in

the art to conclude that using a constitutive promoter (such as the NOS promoter) to transgenically express HR elicitors in plants would not be lethal to the plants. In fact, the vector used by Tampakaki was not a ***pathogen***-inducible promoter, but rather a chemical-inducible expression system (i.e., inducible by tetracycline) (*see* Tampakaki, at pages 1367, left column, and 1373, left column).

The USPTO states that, "[g]iven the state of the art at the time of filing, use of non-inducible promoters would need to be taught by the specification" (Examiner's Answer, at page 6). Applicants respectfully submit that the use of such promoters is indeed taught by the specification at page 36, lines 17-21. However, the USPTO seems to take the view that, in this case, an adequate teaching would require "working examples in which a plant was transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor (harpin) of SEQ ID NO:1, 3, 5, or 7 and a non-pathogen inducible promoter" (Examiner's Answer, at page 7). Applicants disagree.

At the time of filing, the basic techniques and components required to transform a plant with a "foreign" gene were well known in the art. This is evidenced by the teachings of Koncz, Bauer, Beer, Fraley, and Rogers. The current claims specify the use of a non-pathogen inducible promoter. At the time of filing, the skilled artisan would have easily determined the types of promoters that would fall into this category of promoters. In other words, such a selection would not have required undue experimentation to select a non-pathogen inducible promoter that could be used to transform plants. *See* Koncz, Fraley, and Rogers.

For these reasons, applicants respectfully submit that the rejection of claims 41-47, 49-54, 58-73, 75-77, and 80-85 for lack of enablement is improper and should be withdrawn.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: **January 22, 2007**

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